



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,798	10/12/2001	Joseph C. Trautman	ARC 3043 R1	2432
27777	7590	01/11/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

FWH

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/976,798		TRAUTMAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Catherine S. Williams		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 46-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/26/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Objections*

The objection to claim 50 is withdrawn in light of the remarks filed 10/26/05.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 46-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/09184 in view of Kheiri et al (USPN 6,364,889). WO 00/09184 ('184) discloses an apparatus for delivering a substance having one or more needles driven at a high velocity for reducing the amount of pain experienced by the recipient of the substance. The device includes microprotrusions (see figure 5) that transfer an agent into a microslit (inherent) formed in the skin by the microprotrusions. See page 7 lines 8+. The needles are driven by an impact applicator at a velocity of 1-100 m/s into the skin. See page 2 lines 10+. This velocity along with the disclosed mass of the needle and moving parts at preferably 0.3-1 g will result in the claimed energy on impact of 0.05-3 Joules/cm<sup>2</sup>. Agents that can be transferred include drugs, vaccines, etc. The needles are designed to penetrate to a depth of 10 microns.

'184 meets the claim limitations as described above but fails to include striking the stratum corneum in no greater than 10 ms.

However, Kheiri discloses an electronic lancing device that includes the teaching of having an in-stroke portion of a lancing being about 10ms for reducing the pain experienced by the user.

At the time of the invention, it would have been obvious to incorporate the teaching of Kheiri regarding the timing of the in-stroke into the invention of '184 since both devices teach ways to reduce pain to the subject of the device. The motivation for making the incorporation can be found in the overall teaching of '184 in that the entire device and method of using is to reduce the pain experienced by the patient. By incorporating the teaching of Kheiri, the objectives of '184 would be enhanced.

### *Response to Arguments*

Applicant's arguments filed 10/26/05 have been fully considered but they are not persuasive.

I. Applicant argues that there is no motivation to modify the Imprint ('184) impact applicator to strike the stratum corneum with the disclosed impact energy in less than 10 milliseconds to obtain the benefits and unexpected advantages represented by the instant invention.

First, the combination of Imprint with Kheiri relied on motivation other than the benefits of the instant application. Both Imprint and Kheiri are analogous in the art of piercing implements; therefore, a combination is proper. Additionally, both references state that a clear objective of each invention is to reduce pain to the patient upon impact of a piercing element. One skilled in the art would recognize the commonality between the objectives of the two

references and make the combination to achieve no other benefit than that of enhancing the reduction of pain to the patient.

Second, the declaration filed 4/14/05 has been reviewed for a second time. The declaration was filed after a rejection was made by another examiner based on obvious design choice. The emphasis of the declaration is to indicate that the claimed impact energy and time provides several advantages, achieves at least one purpose and solves at least one stated problem. The emphasis of the declaration was to overcome the obvious design choice rejection which is now moot since that rejection is no longer pending. Applicant has not, in the declaration filed 4/14/05, explained how unexpected results data is evidence of non-obviousness over the present rejection above.

II. Applicant argues that the Imprint reference teaches away from the idea of using higher velocities. This argument on its face is confusing. Applicant refers to page two of the Imprint reference. Imprint discusses many different velocity ranges and it is unclear as to what velocity applicant is referring on page two. The rejection above relies on the overall teaching by Imprint of a velocity between 1-100 m/s to achieve the impact energy of 0.05-3 Joules/cm<sup>2</sup> and not the very high velocities mentioned on page two. See page 2 lines 15-16.

III. Applicant argues that Imprint does not teach the claimed needle length and cites one embodiment on page three that references a depth of 10-12 mm. However, the above rejection does not rely on this embodiment. See page 3 lines 27-29 for needles that are designed, i.e. have a length, to penetrate 10µm.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

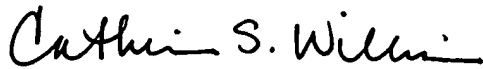
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams

January 6, 2006